Remarks

Claims 1, 2, 8, and 9 are rejected as being anticipated by U.S. Patent No. 6,007,833 to Chudzik et al. (the '833 patent). Claims 3, 4, 10, 11, 13-17, 21-23, and 25 are rejected as obvious over the '833 patent in view of U.S. Patent No. 6,179,862 to Sawhney et al. (the '862 patent). Both rejections are traversed.

The Claimed Invention

Independent claim 1 recites a hydrogel wound dressing that is formed by spraying a liquid composition onto the wound. The liquid composition includes macromers that crosslink to form the hydrogel when they are sprayed upon the wound. The macromers have a PVA backbone and one or more pendant crosslinkable acrylamide groups containing olefinically unsaturated groups. Crosslinking is initiated using a crosslinking initiator. Independent claim 14 recites a method of making a hydrogel wound dressing directly on the wound by spraying a liquid composition onto the wound which crosslinks into the hydrogel as it is sprayed upon the wound. The liquid composition comprises water soluble PVA macromers having one or more pendant crosslinkable acrylamide groups containing olefinically unsaturated groups.

Claim 1 has been amended to clarify that the crosslinking initiator is not bound to either the macromer or to a polymer. Claim 14 has been amended to add the phrase also in claim 1 "and wherein the composition includes a crosslinking initiator that is not bound to a macromer or another polymer". This aspect of the invention is fully supported by the specification- at page 4, lines 10-19, page 9, lines 7-16, and in the examples. New claims 27 and 28 are added- each stating that the crosslinking initiator is a redox couple in solution. Support is found at page 4, lines 10-19, page 9, lines 7-16, and in the examples. New claim 29 has been added – it is essentially the same as claim 1, except instead of stating that the crosslinking initiator is not bound to a macromer or another polymer, claim 29 states that the composition includes an "unbound crosslinking initiator in solution". Support is found at page 4, lines 10-19, page 9, lines 7-16, and in the examples.

A wound dressing formed by spray application of a composition offers several advantages over application via syringe, catheter, or dipping. See page 3, lines 1-12 of the specification. Spray delivery can increase the penetration of the polymer into the wound area thereby potentially making the delivery of active ingredients more efficient. Penetration of the

polymer into the wound bed may also aid in debridement of the wound during dressing changes to accelerate the wound healing process. With spray delivery of an in situ polymerizing polymer, a thin coating can be achieved with excellent coverage of the treated area.

The rejection of claims 1, 2, 8, and 9 over the '833 patent

The '833 patent teaches a crosslinkable macromer system. The system can be used as a wound dressing. The system includes two or more polymer/macromer-pendant polymerizable groups and one or more polymer/macromer-pendant initiator groups. The terms polymer and macromer are used interchangeably. Preferably, the polymerizable group and the initiator group are attached to (pendant from) the same macromer/ polymer- but they may be on different macromers/polymers.

As the Examiner points out in the most recent Office Action, the initiator is bound to either the macromer or to another polymer. It can also be on the backbone of the polymer itself. The point of the invention is to avoid the use of free initiators that can present issues of toxicity, efficacy, and solubility (see col. 2, lines 15-20). To this end, **the initiator is bound to the macromer/polymer**.

The '833 patent does not teach or suggest that the composition is applied to a wound via spraying. The '833 does specify methods of delivery of the composition, contrary to the statement otherwise by the Examiner, and those methods are not inclusive of spray delivery. The Examiner cannot say that the reference teaches the specific means of spray delivery simply because it contains a generic teaching that the composition is applied to a wound.

Claim 1 recites a wound dressing that includes at least two aspects that are not taught by the '833 patent: 1) the use of an unbound initiator and 2) a wound dressing that is applied via spray.

The '833 patent in fact **teaches away** from the claimed invention since it expressly and deliberately avoids the use of an unbound initiator. Claim 1 has been amended herein to more accurately state that the initiator is not bound to a polymer- instead of macromer as was recited before. The point is the same- the initiator is not bound to a polymer, but is free. This is opposite of the point of the invention disclosed by the '833 patent. Since the '833 patent does not teach a composition having a free initiator, it does not anticipate claim 1, or claims dependent thereon.

Claim 1 recites a hydrogel wound dressing formed by spray delivery of a composition to the wound. Claim 1 does not recite an intended use for a composition, as stated by the Examiner, but rather it claims a wound dressing formed via spray. The '833 patent does not teach spray delivery of the composition taught therein. It does teach application by other means (direct liquid application via catheter or syringe and dipping), but it does not disclose spray.

At least these two aspects of the claimed wound dressing (unbound initiator and spray application) are not taught by the '833 patent. Accordingly, claim 1, and claims 2, 8, and 9, dependent thereon, are not anticipated by the '833 patent.

The rejection of claims 3, 4, 10, 11, 13-17, 21-23, and 25 over the '833 patent in view of the '862 patent

The '862 patent teaches a method for forming a tissue adherent barrier in situ using a sprayer to deliver crosslinkable fluids. One of the fluids specifically described as suitable in the method is a solution of a polyethylene glycol (PEG) based macromer. The macromer includes a water soluble core oligomer, having biodegradable extensions that are capped with polymerizable end groups. It is true that PVA is listed as a possible water soluble core oligomer. However, the only macromer specifically discussed is a PEG- oligolactyl-diacrylate macromer which has a PEG core unit, a polyhydroxy acid extension on each end, and an acrylate end group on each end. PEG has only two hydroxyl groups - at each terminus- to which the crosslinkable acrylates can be fastened. The claimed macromers, on the other hand, because they are based on PVA, have crosslinkable groups on pendant chains- chains hanging from the backbone. A tremendous advantage of using PVA rather than PEG is that there are many available hydroxyl groups to which crosslinkable or other groups can be attached, and not just two, as in PEG. Thus, the use of PVA as the backbone of the macromers claimed in the present application offers advantages unexpected and unforeseen by the prior art.

The '862 and '833 patents are cited in combination as rendering claims 3, 4, 10, 11, 13-17, 21-23, and 25 obvious. Applicants agree with the Examiner that the '833 patent does not teach delivery by spray, NO as an active agent, redox initiation, or that the dressing debrides the wound when removed (see the previous Office Action, paragraph spanning pages 4 and 5). As discussed above, the '833 patent also does not teach a composition having an initiator not bound to a macromer/polymer. As was discussed in previous correspondence between the Applicants

and Examiner, the '862 patent does not teach or suggest the PVA based macromers that are used in the present invention.

There exists no reason to combine the teachings of the references. In fact, as discussed above, the '833 patent teaches away from the invention recited in claims 1-4, 8-11, and 13, Moreover, even if the references are combined, the claimed invention does not result. The combined patents do not teach a wound dressing formed by spraying a PVA macromer having one or more pendant crosslinkable groups.

The law requires that there be- in the references themselves- some motivation to combine the references. Nowhere does the '833 patent suggest that it would be beneficial to spray the composition taught therein and form a wound dressing. Nowhere does the '862 patent teach that it would be beneficial to use a PVA macromer having one or more pendant acrylamide groups containing olefinically unsaturated groups.

Conclusion

Reconsideration of the claims as amended is respectfully requested.

Respectfully submitted,

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